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EXAMINER

FORD, JOHN M

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/047592

Applicant(s)

Nobel

Examiner

T.M. Ford

Group Art Unit

1624

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

☒ Responsive to communication(s) filed on 1-21-03

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

☒ Claim(s) 1, 2, 5, 8, 11 and 14 -- 42 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 5, 8, 11 and 14 -- 42 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some\* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

☐ Copies of the certified copies of the priority documents have been received

in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other \_\_\_\_\_

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Applicants response of January 21, 2003, is noted.

The claims in the application are claims 1, 2, 5, 8, 11, and 14--42.

Applicants elected the instances where A is variable a), d), g), j), m), n) and o) the five membered rings.

The restriction requirement is considered necessary here and will be maintained. Claim 1 is huge, even after restriction, ~~Some~~ means of recasting claim 1, so that it could at least be considered, had to be undertaken. Look at the top of page 2 of claim <sup>1</sup>. That is a huge undertaking, in the limited time provided, to determine patentability. That is an enormous claim, therefore, a significant burden.

The Examiner has the right to restrict within a claim. 37 CFR 1.141 calls for one invention per application.

Claim 1 (as filed) constitutes an improper joinder of inventions, as it groups together inventions that are distinct and separately classified, and will support separate patents. Ex parte Markush, 1925 C.D. 126, provided for this claim structure where there was an emergency engendered need, as the substances were "so closely related that they would not support a series of patents". This is not the case here. Therefore, the instant generic claim (as filed) constitutes an improper joinder of inventions; Ex parte Reid, 105 U.S.P.Q. 251; In re Winnek, 73 U.S.P.Q. 225; In re Ruzicka, 66 U.S.P.Q. 226.

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The Examiner has compromised to the restriction of the variables  $2n$  set out in the present claim 1 in regard to a), d), g), j), m), n) and o), as acceptable, even though it is a very large genus.

Restriction is proper under 35 U.S.C. 121. It makes no difference whether the misjoinder occurred in one claim or more than one claim.

Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

That appears in MPEP 2173.05(h). In re Harnish 206 USPQ 300, 305 and 306, footnote 7 sanction a rejection and restriction on the basis of dependent and distinct invention. That is that a reference for one would not constitute a reference for the other(s).

It is far too burdensome on the examiner to expand the search.

This case is now in class 544. A whole multiple area of class 540 would have to be added to expand the search beyond the elected invention.

The restriction is proper.

A Markush-type claim is directed to "independent and distinct inventions," if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim

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with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s).

BNA

Number 486

July 3, 1980

### HIGHLIGHTS

**PTO Has "Perfect Right" To Reject Markush Claims:** Even though there is no statutory basis for doing so. PTO has "perfect right" to reject improper Markush claims, declares U.S. Court of Customs and Patent Appeals.

**PTO HAS "PERFECT RIGHT" TO REJECT IMPROPER MARKUSH CLAIM**  
**(In re Harnisch, 6/12/80) 206 U.S.P.Q. 300.**

**Citing the CCPA's decisions in In re Weber, 580 F.2d 435, 198 USPQ 328 (CCPA 1978), 386 PTCJ A-5, and In re Haas (Haas II), 580 F.2d 641, 198 USPQ 334 (CCPA 1978), 386 PTCJ A-8, the Board of Appeals reversed on grounds that "35 U.S.C. 121 does not form the basis for rejection of a claim\*\*\*." The board then entered a new rejection of the claims as being drawn to improper Markush groups". Relying on "judicially created doctrine, "the board determined that the claimed compounds are not "fictionally equivalent" and "are so dissimilar then to associate them together as a generic group".**

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As is clear from the entire board opinion, what is meant was that it intended to rely on rules, principles, or tenets derivable from the cases it cited which would enable it to determine whether the claims before it were or were not in proper form to be examined for patentability. Our ruling on this point is that it had a perfect right to do so.

[Regarding] appellant's argument that the board should not be allowed to rely solely on judicial precedent, we think it should be clear from our actions in Weber and Haas II that we there recognized the possibility of such a thing as an "improper Markush grouping". We were and are aware that it does not have a specific statutory basis, [but we believe a rejection can be made in appropriate cases].

**PTCJ COMMENT:** Anticipating the likely impact of its decision, the CCPA, in footnote 7, invites the PTO to consider rule making. "Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rule making powers under 35 U.S.C. 6(a), wherein the views of interested parties may be heard".

Claim 1 is rejected under 35 U.S.C. 1st and 2nd paragraphs.

What is intended by heterocyclyl and heteroaryl in the claims?

Heterocyclic is a huge area of Chemistry, that completely overshadows the formula I.

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

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Hetero aryl, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Where is what is intended by applicant supported in the specification with sufficient representative exemplification? Note United Carbon Co., vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention; there are in reality only two basic groups for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by

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specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to have a potential scope or protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here is the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection of the claims. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are notoriously unstable.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1, 3, 4, etc., as each is a different entity, with a separate search.



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These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in the unknown ring.

What are the hetero atoms?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification for the variables sought,<sup>2</sup>

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is pharmaceutical. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

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The heteroaryl expressions in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what is does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 27/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. V.s. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. V.s.. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The heteroaryl expression includes adjacent O/S combinations that are unstable. That open ended breadth cannot be allowed. The claim cannot be completely searched, here, until we know what applicants intend by heteroaryl, see In re Wiggins; 179 USPQ 421. Where is the support in the specification?

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Similarly, the USPTO only recognizes: C,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heterocyclic is not just a substituent; it is a whole body of art, larger than the claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds, without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

In an area of high interferences, you have to think what happens after the application is allowed. Counts are impossible to construct where there is no specific support in the specification for the term as species; In re Ruschig, 154 F.2d 118.

A count cannot be constructed for heterocyclic as it has no species support; Freerksen vs. Gass, 21 USPQ (2nd) 2007.

Claims 2, 5, 8, 11, 14--18 are rejected as being dependent on a rejected.

Claim 19 is rejected for the reasons claim 1 was rejected in regard to: hetero aryl.

Claim 20 tells us what heteroaryl means, fine. However, claims 20--29 cannot be allowed as they are written dependent on a rejected claim.

Claims 30, 34, 35, 36, 37, 38 and 39 is rejected for reasons claim 1 was rejected.

Claims 31--33 are rejected as being dependent on a rejected claim.

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Claims 40--42 are rejected as being dependent on a rejected claim. It cannot be determined that claim 42 is solely directed to the elected invention.

John M. Ford:jmr

February 21, 2003

A handwritten signature in black ink, appearing to read "John M. Ford", written in a cursive style.

JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624